December 7, 2001

The Honorable Christine Todd Whitman
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Dear Administrator Whitman:

I am writing to express my strong reservations about using results from human testing to determine the toxicity of pesticides. According to recent press accounts, these test results are apparently now being used by EPA at the behest of the pesticide industry.[1] According to an industry spokesman, the purpose of their use is to justify the establishment of less stringent safety standards.[2]

Your apparent decision to allow human test results to be used in pesticide regulations is disturbing, and the appearance of secrecy surrounding this decision makes it even more troubling. The decision is wrong on several fronts. First, the scientific benefit of these studies is unclear. Second, the decision to allow pesticides to be tested on humans for the sole purpose of establishing less stringent safety standards raises extraordinarily serious ethical problems. And third, it appears that you have secretly reversed a carefully developed and fully justified EPA policy without giving the public an opportunity to comment or providing any justification for your decision.

The scientific value of the results of these human tests is, at best, negligible. In almost all cases,

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[1]Los Angeles Times, *U.S. Will Use Once-Banned Human Tests* (Nov. 27, 2001); New York Times, *EPA Weighs Pesticide Tests on Humans* (Nov. 28, 2001); Washington Post, *EPA Used Data from Human Pesticide Tests* (Nov. 29, 2001).

[2]Ray McAllister, Vice President for Science and Regulatory Affairs for the American Crop Protection Association, was quoted as saying that without human testing, regulations "end up being more conservative and more restrictive." *U.S. Will Use Once-Banned Human Tests*, *supra* note 1.

human studies rely upon too few subjects to assess the risks to the broader population and its vulnerable members. Since current law dictates that the EPA specifically consider risks to these vulnerable subpopulations, the value of the findings from the human test results is dubious. In addition, experts have indicated that the human testing is unnecessary, as the same information can be obtained using less troubling methods.

The use of human subjects in tests designed to support the establishment of less stringent safety standards for pesticides is also ethically unacceptable. In 1998, EPA convened an expert panel to analyze the scientific and ethical issues surrounding human testing. This expert panel concluded that "[i]f it can be justified at all to expose human subjects intentionally to toxic substances, the threshold of justification for such actions should be very high."[3] The panel also found that "[i]f the use of human subjects in pesticide testing can be justified, that justification cannot be to facilitate the interests of industry or of agriculture, but only to better safeguard the public health."[4] Other international agreements and treaties, including the Nuremburg Code and the Helsinki Declaration, have also indicated that the use of human testing presents severe ethical difficulties, and should only be done under strict conditions and when there are significant benefits to society as a whole.

In the case of the studies that you are using, there is no specific benefit for the general public or for the particular subjects of these tests. The sole benefit of your new human testing policy will accrue to the pesticide industry in the form of weaker regulations than would be established in the absence of your new policy. Thus, there appears to be no ethical standard by which the data from these tests should be allowed.

Finally, I am concerned about the secretive nature of the decision-making process that allowed consideration of data from these human tests. The EPA policy you apparently reversed was based on a public process and followed the guidelines established by a 1998 expert panel of scientists and ethicists. This panel provided detailed guidelines and institutional guarantees to ensure that in the rare cases where human tests were justified, they would be used in an appropriate manner. But your decision appears to have been made in secrecy, with no public deliberation and no opportunity for the public to comment. It does not appear as if you have consulted the guidelines established by the 1998 panel. It was not made public through formal channels, but was instead announced at a meeting of the

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[3]EPA, *Comments on the Use of Data from Testing of Human Subjects: A Report by the Science Advisory Board and the FIFRA Scientific Advisory Panel* (EPA-SAB-EC-00-0017) (Sep. 2000).

[4]*Id.*

American Crop Protection Association, the pesticide industry trade group.[5] And you have offered no justification for the reversal of the previous EPA policy.

In light of this disturbing development in pesticide regulation, I am requesting that you provide me with the following information:

(1) A list of all individuals who you or your staff have met with or communicated with on this topic, including all individuals representing pesticide manufacturers. Please include all correspondence from these individuals.

(2) The analyses, memoranda, or other documents that formed the basis for your decision.

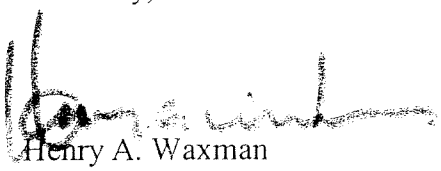
(3) All memoranda or other decisional papers that document your decision to allow the review of pesticide safety data generated through the use of human testing.

(4) A list of all recent pesticide risk assessments where human data has been reviewed in the development of a risk profile. Please include detailed information on what studies were used during these assessments, and on whether these studies meet the institutional guarantees and guidelines recommended by the 1998 expert panel.

(5) A list of all pending pesticide risk assessments where human data will be reviewed in the development of a risk profile. Please include detailed information on the studies under consideration and on whether these studies meet the institutional guarantees and guidelines recommended by the 1998 expert panel.

Please provide answers to these questions and the requested documents no later than December 21, 2001. If you have questions about this important issue, please contact me or Brian Cohen of my staff at 202-225-3976.

Sincerely,



Henry A. Waxman
Ranking Minority Member

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[5] *U.S. Will Use Once-Banned Human Tests, supra* note 1.